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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Per Wollmer

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04/28/2009

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EXAMINER

SAMALA, JAGADISHWAR RAO

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

04/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,828	Applicant(s) WOLLMER ET AL.	
	Examiner JAGADISHWAR R. SAMALA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/20/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election Restriction

Applicant's election with traverse of group I, claims 19-27 in the reply filed on 01/21/2009 is acknowledged. The traversal is on the ground(s) that examining a composition and mouth or nasal spray device containing the microemulsion and method for trapping airborne particles directly or indirectly causing allergic rhinitis in a subject, hence the claimed invention does contribute as a novel invention over the prior art and group I-IV should be examined together. This is not found persuasive because the reversed phase microemulsion in the amended claim is other form of normal oil-in-water emulsion which does not contribute as a novel invention over the prior art Baker et al in view of Wright et al . The restriction requirement is still deemed proper and is therefore made FINAL.

Applicant amendment to claims 19-20 and 31-32 is acknowledged. Claims 19-27 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/20/2008 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 08/20/2008 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Amendment

3. The declaration under 37 CFR 1.132 filed 08/20/2008 is insufficient to overcome the rejection of claim 19-27 based upon 103(a) rejection as set forth in the last Office action because:

Applicant asserts that the declaration submitted illustrate the superiority of the presently claimed subject matter compared to the Baker US 6,506,803 and Wright US 5,618,840 reference.

The allegations were taken considering that the prior art Baker in view of Wright also teaches preparation of emulsions comprising 5 to 50% aqueous phase, 30 to 90% of oil phase and 3 to 15% of surfactant and glycerol esters including glycerol monooleate and oils useful in forming the oily discontinuous phase include a broad spectrum of water-immiscible materials such as sesame oil and hence, being useful as a stable antibacterial emulsion for inactivating bacterial, particularly gram negative bacteria and for decreasing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms. Applicant argues that the advantages of reversed phase microemulsions include retention of their structure on mixing with an aqueous solution which conveys the ability to form a barrier layer, sufficient

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experimental data was not provided. The prior art reference teaches that microemulsion comprises about 35% of non-polar or oil phase and 10% of aqueous or water phase and would result in oil in water phase i.e., reversed phase microemulsion. Thus the structure provided by the prior art would maintain the negative spontaneous curvature and can be used in biological fluids for inactivating bacteria and for decreasing the infectivity of pathogenic organisms in foodstuffs.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 19-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claims 19 and 20 to recite "reversed phase" microemulsion. This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. The specification discloses a composition comprising glycerol monooleate 34%, propylene glycol 23%, PEG 18%, sesame oil 11%, and saline solution 10% as a microemulsion suitable for entrapping airborne particles. However, the specification does not recite "reversed phase" microemulsion as claimed.

In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker, Jr. et al (US 6,506,803) in view of Wright (US 6,618,840).

Applicant claims are drawn to a reversed phase microemulsion comprising 5 to 35 wt% of a non-polar animal or vegetable oil; 10 to 55 wt% of at least one polar solvent; at least one surfactant; and 20 to 50 wt% of a monoacyl glycerol.

Baker discloses an emulsion composition comprising 5 to 50 wt% aqueous phase which would read on polar solvent; 30 to 90 wt % oil phase; and 3 to 15 wt% of surfactant such as polysorbate detergents sold under the trademarks Tween 80. The

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aqueous phase comprises water at a pH of about 4 to 10, preferably about 6 to 8 (col. 10 lines 50-65 and col. 11 lines 30-33). The surfactant polysorbate such as Tween 80 added to emulsion would obviously provide required hydrophilic-hydrophobic balance. Same compound as recited in the instant claims should have same property and would result in emulsion having HLB value as claimed. The emulsion composition comprises glycerol monooleate in the initial oil phase and suitable carriers such as fatty acids, polyethylene glycols, wherein water to oil phase ratio ranges from 4:1 which would read on reversed phase microemulsion (col. 14). The emulsion compositions can be administered in any effective pharmaceutically acceptable forms to warm blood animals (humans), such as oral, nasal, buccal, rectal, vaginal, topical or nasal spray or in any other form effective to deliver active composition (col. 23 lines 28-32). Additional disclosure includes that compositions are useful for decreasing the infectivity of pathogenic organisms in foodstuffs, in particular, decreased pathogenic organism infectivity, morbidity, and mortality is accomplished by contacting the pathogenic organism with an emulsion comprising an oil, an organic solvent, and a surfactant dispersed in an aqueous phase. Additional advantage of emulsions is that they may readily be diluted with water to a desired concentration and stay stable and retain their structure unchanged (col. 5 lines 25-41).

Baker meets the claim limitation but fails to disclose specific amounts of mono acyl glycerol component such as glycerol monooleate and vegetable oil such as sesame oil in the emulsion.

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Wright discloses an antibacterial oil-in-water emulsion comprising droplets of an oily phase such as soybean oil, sesame oil, fish oil and like, and mono glycerol ester selected from group consisting of glycerol monooleate (12 to 21 wt %) and glycerol monostearate. The emulsions can be administered to individuals, for example, orally to treat or prevent *Helicobacter pylori* infection (abstract and col. 6 lines 44-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate glycerol monooleate and vegetable oil such as sesame oil into the Baker's emulsion suitable for pharmaceutical administration made up of an antibacterial emulsion to inhibit the growth of bacteria. The person of ordinary skill in the art would have been motivated to make these modifications, because Baker teaches that emulsion prepared are useful for decreasing the infectivity of pathogenic organisms in foodstuffs, in particular, decreased pathogenic organism infectivity, morbidity, and mortality is accomplished by contacting the pathogenic organism. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success because both Baker and Wright teaches microemulsions that can be used in the same field of endeavor such as inactivating a wide variety of microorganisms including bacteria, bacterial spores, fungi, fungal spores and enveloped viruses.

Conclusion

1. No claims are allowed at this time.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
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sjr

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